The effect of diet-induced changes in intestinal mucus and microbiota composition on the development of type 2 diabetes and non-alcoholic fatty liver disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20944

Source
NTR

Brief title
DIAMOND-study

Health condition

diabetes; NAFLD; obesity; obesitas

Sponsors and support

Primary sponsor: Maxima Medical Centre, Veldhoven, the Netherlands
Source(s) of monetary or material Support: Maxima Medical Centre, Veldhoven, the Netherlands
Maastricht University Medical Centre, Maastricht, the Netherlands

Intervention

Outcome measures

Primary outcome

fecal and intestinal microbiota composition

mucus composition, Paneth cell phenotype

Secondary outcome

body weight, BMI, abdominal circumference, composition diet, ...

Study description

Study objective

Modulation of Paneth cell and/or goblet cell function by increased lipid intake underlies the microbiota alterations that promote obesity, type 2 diabetes and non-alcoholic fatty liver disease.

Study design

Preoperative (baseline), 12 months postoperative

Intervention

Group 1: Roux-en-Y gastric bypass

Group 2: laparoscopic cholecystectomy

Group 3: upper GI endoscopy

Contacts

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Eligibility criteria

Inclusion criteria

Group 1

BMI > 40 kg/m2 of >35 kg/m2 with comorbidities

Age between 18 and 60 years

Group 2 and 3

BMI 20-25 kg/m2

Age between 18 and 60 years

Exclusion criteria

Group 1

Type 1 diabetes

Alcohol or drug abuse according to DSM-V

Inflammatory disease, such as auto-immune disease

Degenerative diseases

Doctor-prescribed use of corticosteroids or prednisolon

Use of antibiotics in the three months prior to surgery

Group 2 and 3

Type 1 or type 2 diabetes

Cachexia, defined as weight loss (<5% in a month or >10% in 6 months) or a BMI <20kg/m2

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-02-2016
Enrollment:	228
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47711
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5540
NTR-old	NTR5660
CCMO	NL52416.015.15
OMON	NL-OMON47711

Study results